



## GE Healthcare 510(k) Premarket Notification Submission

#### 510(k) Summary

In accordance with 21 CFR 807.92 the following summary of information is provided:

<u>Date:</u> January 19, 2012

Submitter: GE Healthcare [GE Vingmed Ultrasound AS]

Strandpromenaden 45 N-3191, Horten, Norway

Primary Contact Person: Bryan Behn

Regulatory Affairs Manager

GE Healthcare T:(414)721-4214 F:(414)918-8275

Secondary Contact Person: Jan Tore Thollefsen

Regulatory Affairs Leader GE Vingmed Ultrasound AS

T:(+47)3302-1269 F:(+47)3302-1357

Device: Trade Name: Vivid E9 Diagnostic Ultrasound System

Common/Usual Name: Vivid E9

Classification Names: Class II

Product Code: Ultrasonic Pulsed Doppler Imaging System. 21CFR 892.1550 90-IYN

Ultrasonic Pulsed Echo Imaging System, 21CFR 892.1560, 90-IYO Diagnostic Ultrasound Transducer, 21 CFR 892.1570, 90-ITX

<u>Predicate Device(s):</u> K101149 Vivid E9 Diagnostic Ultrasound System

K102388 Vivid i / Vivid q Diagnostic Ultrasound System

K081921 6Tc Transducer (Vivid E9)

Device Description: GE Vivid E9 is a Track 3 diagnostic ultrasound system, which is

primarily intended for cardiac imaging and analysis, but which also includes vascular and general radiology applications. The Vivid E9 incorporates a variety of electronic array transducers operating in linear, curved linear, sector/phased array or matrix array format, including two dedicated CW transducers and several real time 3D transducers. It consists of a mobile console with keyboard control panel; color LCD/TFT touch panel, LCD color video display and optional image storage and printing devices. It provides high performance ultrasound imaging and analysis and has comprehensive networking and DICOM

capability.



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The system level clinical applications, imaging modes and device description remain unchanged compared to the predicate device Vivid E9 K101149. This modification to the predicate device adds additional software features and applies Real time 3D imaging to the Transesophageal application and additionally adds the 6VT-D 4D Transesophageal transducer.

Intended Use: GE Vivid E9 ultrasound system is a general-purpose ultrasound system, specialized for use in cardiac imaging. It is intended for use by, or under the direction of a qualified physician for ultrasound imaging and analysis of Fetal; Abdominal (including renal and GYN); Pediatric; Small Organ (breast, testes, thyroid); Neonatal Cephalic; Adult Cephalic; Cardiac (adult and pediatric); Peripheral Vascular (PV); Musculo-skeletal Conventional; Urology (including prostate), Transesophageal; Transrectal (TR); Transvaginal (TV); and Intraoperative (abdominal, thoracic, & vascular).

#### Technology:

The Vivid E9 employs the same fundamental scientific technology as its predicate devices.

#### Determination of Substantial Equivalence:

#### Summary of Non-Clinical Tests:

The device has been evaluated for acoustic output safety, measurement accuracy, biocompatibility. cleaning disinfection effectiveness as well as thermal, electrical. electromagnetic, and mechanical safety, and has been found to conform to applicable medical device safety standards. The Vivid E9 and its applications comply with voluntary standards:

- 1. IEC60601-1, Medical Electrical Equipment Part 1: General Requirements for Safety.
- 2. UL60601-1, Medical Electrical Equipment Part 1: General Requirements for Safety.
- 3. IEC60601-1-2, Medical Electrical Equipment Part 1-2: General Requirements for Safety - Collateral Standard: Electromagnetic Compatibility Requirements and Tests
- 4. IEC60601-2-37, Medical Electrical Equipment Part 2-37: Particular Requirements for the Safety of Ultrasonic Medical Diagnostic and Monitoring Equipment
- 5. NEMA UD 3, Standard for Real Time Display of Thermal and Mechanical Acoustic Output Indices on Diagnostic Ultrasound Equipment:
- 6. ISO 10993-1, Biological evaluation of medical devices Part 1:

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Evaluation and testing within a risk management process. (Biocompatibility)

7. NEMA PS 3.1 - 3.20, Digital Imaging and Communications in Medicine (DICOM) Set. (Radiology)

The following quality assurance measures were applied to the development of the system:

- Risk Analysis
- Usability Analysis
- Requirement Reviews
- Design Reviews
- Testing on unit level (Module verification)
- Integration testing (System verification)
- Final Acceptance Testing (Validation)
- Performance testing (Verification)
- Safety testing (Verification)

#### **Summary of Clinical Tests:**

The subject of this premarket submission, Vivid E9, did not require clinical studies to support substantial equivalence.

Conclusion:

GE Healthcare considers the Vivid E9 to be as safe, as effective, and performance is substantially equivalent to the predicate device(s).



Food and Drug Administration 10903 New Hampshire Avenue Silver Spring, MD 20993

APR 1 9 2012

GE Vingmed Ultrasound AS % Mr. Bryan Behn Regulatory Affairs Manager GE Healthcare GE Medical Systems Ultrasound and Primary Care Diagnostic, LLC 9900 W. Innovation Drive, RP-2138 WAUWATOSA WI 53226

Re: K120201

Trade/Device Name: Vivid E9 Diagnostic Ultrasound System

Regulation Number: 21 CFR 892.1550

Regulation Name: Ultrasonic pulsed doppler imaging system

Regulatory Class: II

Product Code: IYN, IYO, and ITX

Dated: January 19, 2012 Received: January 23, 2012

#### Dear Mr. Behn:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

This determination of substantial equivalence applies to the following transducers intended for use with the Vivid E9 Diagnostic Ultrasound System, as described in your premarket notification:

	Transducer Model Number	•	
ML6-15-D	11L-D	•	6VT-D
12S-D	M4S-D		6T or 6Tc
4V-D	M5S-D		9T
i13L	6S-D		P2D
4C-D	3V-D		P6D
9L-D	E8C-D		

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the <u>Federal Register</u>.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus permits your device to proceed to market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to <a href="http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm">http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm</a> for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to

http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

If you have any questions regarding the content of this letter, please contact Joshua Nipper at (301) 796-6524.

Sincerely Yours,

Janine M./Morris

Acting Director

Division of Radiological Devices

Office of In Vitro Diagnostic Device

**Evaluation and Safety** 

Center for Devices and Radiological Health



510(k) Number

#### **GE** Healthcare

Traditional 510(k) Premarket Notification GE Vivid E9, January 19, 2012

510(k) Number (if known): Device Name: Vivid E9 Diagnostic Ultrasound System Indications for Use: GE Vivid E9 ultrasound system is a general-purpose ultrasound system, specialized for use in cardiac imaging. It is intended for use by, or under the direction of a qualified physician for ultrasound imaging and analysis of Fetal; Abdominal (including renal and GYN); Pediatric; Small Organ (breast, testes, thyroid); Neonatal Cephalic; Adult Cephalic; Cardiac (adult and pediatric); Peripheral Vascular (PV); Musculo-skeletal Conventional; Urology (including prostate), Transesophageal; Transrectal (TR); Transvaginal (TV); and Intraoperative (abdominal, thoracic, & vascular). Prescription Use: X AND/OR Over-The-Counter Use: N/A (Part 21 CFR 801 Subpart D) (Part 21 CFR 801 Subpart C) (PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED) Concurrence of CDRH, Office of In Vitro Devices (OIVD) (Division Sign-Off) Division of Radiological Devices Office of In Vitto Diagnostic Device Evaluation and Safety



Traditional 510(k) Premarket Notification GE Vivid E9, January 19, 2012

### Diagnostic Ultrasound Indications for Use Form GE Vivid E9 Ultrasound System

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

					Mode	of Ope	eration				
Clinical Application Anatomy/Region of Interest	В	М	PW Doppler	CW Doppler	Color Doppler	Color M Doppler	Power Doppler	Combined Modes	Harmonic Imaging	Coded Pulse	RT3D Mode*
Ophthalmic											
Fetal / Obstetrics	Р	Р	Р	Р	Р	Р	Р	Р	P	P	Р
Abdominal <sup>[1]</sup>	Р	Р	Р	Р	Р	Р	Р	Р	Р	Р	. P
Pediatric	Р	Р	P	Р	Р	₽	P	P	Р	Р	P
Small Organ <sup>[2]</sup>	Р	Р	.P		P	P	P	P	P	Р	
Neonatal Cephalic	Р	. <b>P</b>	Р	Р	Р	P	Р	Р	₽	P	
Adult Cephalic	Р	Р	Р	Р	P	Р	Р	Р	P	P	Р
Cardiac <sup>[3]</sup>	P	P	P	Р	Р	Р	Р	Р	P	P	P
Peripheral Vascular	Р	P	P	Р	P	P	Р	P	P	P	
Musculo-skeletal Conventional	P	Р	Р		P	P	P	P	Р	P	
Musculo-skeletal Superficial											
Other <sup>[4]</sup>	P	Р	Р	Р	Р	Р	P	P	P	P	Р
Exam Type, Means of Access											
Transesophageal	Р	P	Р	P	Р	P	P	P	Р	P	N
Transrectal	Р	Р	Р		Р	Р	Р	P		P	
Transvaginal	Р	P	Р		Р	Р	P	P		P	
Transuretheral										=	
Intraoperative <sup>[5]</sup>	Р	Ρ,	Р		P	Р	Р	Р	P	Р	
Intraoperative Neurological											
Intravascular											
Laparoscopic										<u> </u>	<u> </u>

N = new indication; P = previously cleared by FDA; E = added under Appendix E

Notes: [1] Abdominal includes renal, GYN/Pelvic

- [2] Small organ includes breast, testes, thyroid.
- [3] Cardiac is Adult and Pediatric.
- [4] Other use includes Urology/Prostate
- [5] Intraoperative includes abdominal, thoracic (cardiac), and vascular (PV).
- [\*] Combined modes are B/M, B/Color M, B/PWD.or CWD, B/Color/PWD or CWD, B/Power/PWD.
- [\*] RT3D is Realtime 3D / 4D volume tissue scan acquisition (with or w/o color flow);

System provides real-time 3D and 4D acquisition when used with special 4D probes.

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Prescription User (Per 21 CFR 801.109)

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(Division Sign-9#)
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Office of In Witro Diagnostic Device Evaluation and Safety

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Traditional 510(k) Premarket Notification GE Vivid E9, January 19, 2012

#### Diagnostic Ultrasound Indications for Use Form

#### GE Vivid E9 with ML6-15-D Transducer

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

		Mode of Operation											
Clinical Application  Anatomy/Region of Interest	В	М	PW Doppler	CW Doppler	Color Doppler	Color M Doppler	Power Doppler	Combined Modes	Harmonic Imaging	Coded Pulse	RT3D Mode*		
Ophthalmic										•			
Fetal / Obstetrics								·					
Abdominal			_										
Pediatric <sup>[2]</sup>	Р	Р	P		Р.	Р	P	Р	Р	P			
Small Organ <sup>[1][2]</sup>	P	Р	P		P	P	Р	P	P	P			
Neonatal Cephalic	Р	Р	Р		Р	P	Р	Р	. Р	P			
Adult Cephalic			<u></u>										
Cardiac Adult										,	_		
Cardiac Pediatric		_											
Peripheral Vascular <sup>[2]</sup>	Р	. Р	Р		Р	Р	P_	Р	Р	P			
Musculo-skeletal Conventional[2]	P	P	Р		P	P	Р	Р	P	P			
Musculo-skeletal Superficial													
Other													
Exam Type, Means of Access													
Transesophageal													
Transrectal					<u> </u>								
Transvaginal	·				,								
Transurethral													
Intraoperative													
Intraoperative Neurological													
Intravascular													
Laparoscopic				<u> </u>	<u> </u>				<u></u> _				

N = new indication, P = previously cleared by FDA; E = added under Appendix E

Notes: [1] Small organ includes breast, testes, thyre	
Notes: 111 Small ordan inclines oreast Testes Toylo	id.

- [2] Needle guidance imaging
- [\*] Combined modes are B/M, B/Color M, B/PWD or CWD, B/Color/PWD or CWD, B/Power/PWD.
- [+] RT3D is Realtime 3D / 4D volume tissue scan acquisition (with or w/o color flow);

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Traditional 510(k) Premarket Notification GE Vivid E9, January 19, 2012

#### Diagnostic Ultrasound Indications for Use Form

#### **GE Vivid E9 with 12S-D Transducer**

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

					Mode	of Op	eratior	1			_
Clinical Application Anatomy/Region of Interest	В	. M	PW Doppler	CW Doppler	Color Doppler	Color M Doppler			Harmonic Imaging	Coded Pulse	RT3D Mode
Ophthalmic											
Fetal / Obstetrics											
Abdominal		ļ									
Pediatric	Р	Р	Р	Р	Р	Р	Р	Р	Р	Р	
Small Organ		ļ	1								
Neonatal Cephalic	Р	Р	P	P	Р	Р	Р	Р	Р	Р	
Adult Cephalic						<u> </u>					
Cardiac <sup>[1]</sup>	Р	P	P	Р	P	Р	Р	P	Р	P	
Peripheral Vascular							<u> </u>				
Musculo-skeletal Conventional					ļ	,			<u> </u>	·	
Musculo-skeletal Superficial				<u> </u>		٠	ļ				
Other								ļ			
Exam Type, Means of Access			-	<u></u>							
Transesophageal							!				<u> </u>
Transrectal								ļ			
Transvaginal		<u> </u>			,						
Transuretheral				<u> </u>							
Intraoperative (specify)					ļ	ļ					
Intraoperative Neurological										<u>:</u>	<b>-</b>
Intravascular											
Laparoscopic				}	l						<u> </u>

N = new indication; P = previously cleared by FDA; E = added under Appendix E

Notes:	111	Cardiac	is	Adult	and	Pediatric.
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- [\*] Combined modes are B/M, B/Color M, B/PWD, B/Color/PWD, B/Power/PWD.
- [+] RT3D is Realtime 3D / 4D volume tissue scan acquisition (with or w/o color flow);

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Traditional 510(k) Premarket Notification GE Vivid E9, January 19, 2012

#### Diagnostic Ultrasound Indications for Use Form

#### **GE Vivid E9 with 4V-D Transducer**

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

					Mode	of Ope	eration				
Clinical Application  Anatomy/Region of Interest	В	М	PW Doppler	CW Doppler	Color Doppler	Color M Doppler		Combined Modes	Harmonic Imaging	Coded Pulse	RT3D Mode
Ophthalmic											
Fetal / Obstetrics	Р	P	P	Р	P	P	Р	Р	Р	Р	P
Abdominal <sup>[1]</sup>	Р	P	P	Р	Р	Р	Р	P	P	Р	Р
Pediatric	Р	P	Р	Р	Р	Р	Р	Р	P.	Р	P
Small Organ											
Neonatal Cephalic				<u> </u>							ļ
Adult Cephalic	P	Р	P	P	Р	Р	· P	Р	P	P	Р
Cardiac <sup>[2]</sup>	P	P	P	Р	Р	Р	P	Р	Р	P	Р
Peripheral Vascular							ļ				
Musculo-skeletal Conventional											
Musculo-skeletal Superficial										<u> </u>	
Other <sup>[3]</sup>	Р	P	Ρ.	Р	P	P	P	Р	Р	Р	Р
Exam Type, Means of Access		٠.						<u></u>			
Transesophageal										·	
Transrectal		,			,						<u> </u>
Transvaginal											ļ
Transuretheral									,		
Intraoperative (specify)											
Intraoperative Neurological						ļ ,					
Intravascular			<u> </u>								
Laparoscopic			] -	<u> </u>					-		

N = new indication; P = previously cleared by FDA; E = added under Appendix E

Notes: [1] Abdominal includes renal, GYN/Pel-
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- [2] Cardiac is Adult and Pediatric.
- [3] Other use includes Urology/Prostate
- [\*].Combined modes are B/M, B/Color M, B/PWD, B/Color/PWD, B/Power/PWD.
- [+] RT3D is Realtime 3D / 4D volume tissue scan acquisition (with or w/o color flow);

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510K K 3030



Traditional 510(k) Premarket Notification GE Vivid E9, January 19, 2012

### Diagnostic Ultrasound Indications for Use Form GE Vivid E9 with i13L Transducer

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

					Mode	of Op	eration	1			
Clinical Application  Anatomy/ Region of Interest	В	М	PW Doppler	CW Doppler	Color Doppler	Color M Doppler		Combined Modes	Harmonic Imaging	Coded Pulse	RT3D Mode
Ophthalmic			<u> </u>							`	
Fetal / Obstetrics	•										<u> </u>
Abdominal <sup>[1]</sup>	Р	Р	Р		Р	P	Р	P		P	<u> </u>
Pediatric						ļ		ļ			<u> </u>
Small Organ (specify)				<u></u>	ļ			ļ			<b> </b>
Neonatal Cephalic		<u> </u>			·	,				ļ	<del> </del> -
Adult Cephalic					<u> </u>	<u>'</u>					<del>                                     </del>
Cardiac <sup>[2]</sup>	Р	Р	P	ļ	Р	Р	P	Р		P	<u> </u>
Peripheral Vascular						ļ		_			<b>↓</b>
Musculo-skeletal Conventional			ļ	<u> </u>		<u> </u>	<u> </u>	<u> </u>		<u> </u>	-
Musculo-skeletal Superficial			ļ	<u> </u>							<u> </u>
Other (specify)				<u> </u>		ļ <u>-</u>	<u> </u>		<u> </u>	ļ <u> </u>	<b>↓</b> —
Exam Type, Means of Access				ļ	ļ	<u> </u>					<u> </u>
Transesophageal		ļ	<u> </u>	<u> </u>	<u> </u>	<u> </u>	ļ	ļ	ļ	<b>↓</b>	—
Transrectal						ļ		<u> </u>		<del> </del>	<b>├</b>
Transvaginal					<u> </u>			<del>                                     </del>			
Transuretheral		<u> </u>		<u> </u>	ļ			ļ .	ļ <u>.</u>	ļ	<del> </del>
Intraoperative <sup>[3]</sup>	Р	P	Р		Р	P	P	P		Р	<del> </del> -
Intraoperative Neurological		<u> </u>		-	-	↓	ļ	<u> </u>		<b> </b>	<del> </del>
Intravascular		<u> </u>		<u> </u>		<u> </u>		ļ	ļ <u> </u>	<del>  -</del>	<del> </del>
Laparoscopic				l				<u> </u>		<u> </u>	<u> </u>

N = new indication; P = previously cleared by FDA; E = added under Appendix E

Notes: [1] Abdominal includes renal, GYN/Pelvic

- [2] Cardiac is Adult and Pediatric via Intraoperative;
- [3] Intraoperative includes abdominal, thoracic, and vascular.
- [\*] Combined modes are B/M, B/Color M, B/PWD, B/Color/PWD, B/Power/PWD.
- [ ] RT3D is Realtime 3D / 4D volume tissue scan acquisition (with or w/o color flow);

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Traditional 510(k) Premarket Notification GE Vivid E9, January 19, 2012

### Diagnostic Ultrasound Indications for Use Form GE Vivid E9 with 4C-D Transducer

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

					Mode	of Op	eratio	n			
Clinical Application  Anatomy/Region of Interest	В	М	PW Doppler	CW Doppler	Color Doppler	Color M Doppler		Combined Modes	Harmonic Imaging	Coded Pulse	RT3D Mode*
Ophthalmic							<u> </u>		ļ 		
Fetal / Obstetrics	P	Р	Р		Р	P	Р	Р	Р	Р	
Abdominal	Р	P	P	<u> </u>	P	P	Р	Р	P_	P	
Pediatric	P	Р	Р		Р	P	Р	Р	Р	Р	<u> </u>
Small Organ <sup>[2]</sup>									<u> </u>		<u> </u>
Neonatal Cephalic				ļ							<u> </u>
Adult Cephalic				·				<u> </u>			<u> </u>
Cardiac				ļ						·	<u> </u>
Peripheral Vascular	Р	P	Р	<u> </u>	P	P_	P	P	Р	P_	ļ
Musculo-skeletal Conventional				<u> </u>		<u> </u>			ļ	<u> </u>	<u> </u>
Musculo-skeletal Superficial	_		ļ ·	<u> </u>		ļ	<u> </u>	·			
Other <sup>[4]</sup>	Р	Р	P		Р	P	Р	Р	P	P_	ļ
Exam Type, Means of Access			<u> </u>			<u> </u>		ļ	<u> </u>		<b>├</b> ──
Transesophageal		<u> </u>	ــــــ					ļ	<u> </u>	<u> </u>	
Transrectal				<u></u>		<u> </u>	<u> </u>	ļ	<u> </u>	<u> </u>	<del> </del> -
Transvaginal				<u> </u>		<u> </u>				<u> </u>	<u> </u>
Transuretheral		ļ		· .		<u> </u>		ļ	<u> </u>	<u> </u>	ļ
Intraoperative (specify)			<u> </u>	<u> </u>	<u> </u>	<u> </u>		<del> </del> -			₩-
Intraoperative Neurological						<u> </u>	<del> </del> -				<del> </del>
Intravascular					<del> </del>	ļ. <u> </u>		<u> </u>		<u> </u>	<del> </del>
Laparoscopic						1	<u> </u>	<u> </u>	<u> </u>	<u> </u>	<u> </u>

N = new indication; P = previously cleared by FDA; E = added under Appendix E

Notes:	[2]	Small	organ	includes	breast,	testes,	thyroid.
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- [4] Other use includes Urology/Prostate
- [\*] Combined modes are B/M, B/Color M, B/PWD, B/Color/PWD, B/Power/PWD.
- [ ] RT3D is Realtime 3D / 4D volume tissue scan acquisition (with or w/o color flow);

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Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OIVD)

Prescription User (Per 21 CFR 801.109)

Division of Radiological Devices

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Traditional 510(k) Premarket Notification GE Vivid E9, January 19, 2012

### Diagnostic Ultrasound Indications for Use Form GE Vivid E9 with 9L-D Transducer

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

·					Mode	of Op	eratio	n			<u> </u>
Clinical Application  Anatomy/Region of Interest	В	M	PW Doppler	CW Doppler	Color Doppler	Color M Doppler	Power Doppler	Combined Modes	Harmonic Imaging	Coded Pulse	RT3D Mode*
Ophthalmic						ļ					
Fetal / Obstetrics			<u> </u>	<u> </u>							
Abdominal						<u>.</u>					
Pediatric	<u> P</u> _	P_	P		Р	P	Р	Р	Р	P_	<u> </u>
Small Organ <sup>[2]</sup>	Р	Р	Р		P	P	P_	P_	P	P_	
Neonatal Cephalic				ļ			<u> </u>		<b></b> _	<u> </u>	<del> </del>
Adult Cephalic						<b>_</b>		<u> </u>	<u> </u>		
Cardiac					<u> </u>	<u> </u>	<u> </u>	<u> </u>	<u> </u>		<u></u>
Peripheral Vascular	P	P_	Р	<u> </u>	Р	P	P	<u> </u>	Р	P	ļ
Musculo-skeletal Conventional	P	P	Р	<u> </u>	P	P	Р	P	Р	P	ļ. — ·
Musculo-skeletal Superficial			<u> </u>			<u> </u>	<u> </u>	ļ			
Other <sup>[4]</sup>		<u> </u>		<u> </u>		<u> </u>		<del> </del> -		<u> </u>	<b>├</b>
Exam Type, Means of Access	<u> </u>	ļ		<u> </u>		<u> </u>	<u> </u>	<del> </del>	<u> </u>	<u> </u>	<del></del>
Transesophageal		<u> </u>		<u> </u>		<u> </u>	<del> </del>		_	<u> </u>	-
Transrectal		<u> </u>	<b>_</b>		<u> </u>	<u> </u>	<del>                                     </del>	<u> </u>			<b>├</b> —
Transvaginal			<u> </u>	_		<del> </del> -		<del> </del> -		<del>                                     </del>	<u> </u>
Transuretheral	<u>.                                    </u>	<u> </u>		<u> </u>	<u> </u>	<u> </u>	+-	-	<u> </u>	<del> </del> -	
Intraoperative (specify)		ļ <u>.</u>			ļ	ļ	-	ļ.·		<del> </del>	
Intraoperative Neurological				<b> </b>	<b>.</b>			<u> </u>		<b>↓</b> —	
Intravascular	<u> </u>				ļ	<del> </del>		<u> </u>	ļ	<del> </del>	1
Laparoscopic	<u> </u>	<u> </u>		J	l	<u> </u>	- 45.4 5	<u> </u>	<u> </u>		

N = new indication; P = previously cleared by FDA; E = added under Appendix E

	TOT Con-II assoc	includes breast,	tactae thyroid	
MULDE.	171 Sman ordan	Incaudes dieast	Legies, milion	,,

- [\*] Combined modes are B/M, B/Color M, B/PWD, B/Color/PWD, B/Power/PWD.
- ·[•] RT3D is Realtime 3D / 4D volume tissue scan acquisition (with or w/o color flow);

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- h/20201



Traditional 510(k) Premarket Notification GE Vivid E9, January 19, 2012

### Diagnostic Ultrasound Indications for Use Form GE Vivid E9 with 11L-D Transducer

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

					Mode	of Op	eratio	n			
Clinical Application  Anatomy/Region of Interest	В	М	PW Doppler	CW Doppler	Color Doppler	Color M Doppler	Power Doppler		Harmonic Imaging	Coded Pulse	RT3D Mode
Ophthalmic											
Fetal / Obstetrics				<u> </u>							
Abdominal						<u> </u>			<u> </u>		
Pediatric	<u> P</u>	P_	Р		Р	Р	Р	Р	Р	Р	
Small Organ <sup>[2]</sup>	Р	P	P		P	Р	Р	P	Р	·P	
Neonatal Cephalic				ļ							<u> </u>
Adult Cephalic			<u> </u>								<u> </u>
Cardiac				ļ		ļ					ļ.——
Peripheral Vascular	<u>P</u> _	P	P		P	Р	Р	Р	P	Р	<u> </u>
Musculo-skeletal Conventional	P	P	P_	ļ	Р	P	P	P	Р	P	-
Musculo-skeletal Superficial		ļ	\ <u></u>								ļ
Other <sup>[4]</sup>		ļ <u>.</u>								<u></u>	<u> </u>
Exam Type, Means of Access			· · ·			ļ					
Transesophageal	·		<u> </u>	<u> </u>		<u> </u>			<u> </u>		<del> </del>
Transrectal		<u> </u>				ļ			ļ	<u> </u>	<b>-</b>
Transvaginal		ļ	<del>  -</del>	<u> </u>					<u> </u>	<u> </u>	<u> </u>
Transuretheral		ļ		<u> </u>			<u> </u>		<u> </u>		<del>  -</del> -
Intraoperative <sup>[5]</sup>	Р	P	P	<b>_</b>	Р	P	Р	P_	P	P	<del>                                     </del>
Intraoperative Neurological		<u> </u>	<del>                                     </del>	ļ	<u> </u>		ļ		ļ	<u> </u>	<del>  -</del>
Intravascular		<u> </u>			<u> </u>			· · · <u> </u>	<u> </u>		<del> </del>
Laparoscopic							<u> </u>	<u> </u>	<u> </u>	<u> </u>	<u> </u>

N = new indication; P = previously cleared by FDA; E = added under Appendix E

Notes: [2] Small organ includes breast, testes, thy
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- [5] Intraoperative includes abdominal, thoracic (cardiac), and vascular (PV).
- [\*] Combined modes are B/M, B/Color M, B/PWD, B/Color/PWD, B/Power/PWD.
- [•] RT3D is Realtime 3D / 4D volume tissue scan acquisition (with or w/o color flow);

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Traditional 510(k) Premarket Notification GE Vivid E9, January 19, 2012

#### Diagnostic Ultrasound Indications for Use Form GE Vivid E9 with M4S-D Transducer

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

					Mode	of Op	eratio	n			·
Clinical Application  Anatomy/Region of Interest	В	М	PW Doppler	CW Doppler	Color Doppler	Color M Doppler	Power Doppler	Combined Modes	Harmonic Imaging	Coded Pulse	RT3D Mode
Ophthalmic											<u> </u>
Fetal / Obstetrics	Р_	Р.	P	P	Р	Р	P	Р	Р	Р	
Abdominal	Р	Р	P	. Р	P	Р	Р	Р	Р	Р	<u> </u>
Pediatric	Р	Р_	P	P	P	Р	P	Р	Р	Р	ļ
Small Organ <sup>[2]</sup>								_	ļ		
Neonatal Cephalic					<u> </u>	· ·		ļ		<u> </u>	
Adult Cephalic	Р	Р	Р	Р	P	P	Р	Р	P_	Р	
Cardiac <sup>[3]</sup>	Р	P	P	Р	P	P_	P	P	Р	Р	<u> </u>
Peripheral Vascular				<u> </u>	ļ						ļ
Musculo-skeletal Conventional					ļ	<u> </u>					ļ
Musculo-skeletal Superficial			ļ	ļ		<u> </u>				ļ	<del> </del>
Other <sup>[4]</sup>	_ P	Р	Р	Р	P	Р	P	Р	Р	Р_	<u> </u>
Exam Type, Means of Access			ļ	ļ	ļ	<u> </u>	<u> </u>			<u> </u>	
Transesophageal						<del> </del>	ļ		ļ <del></del>		<u> </u>
Transrectal		,				<b>↓</b>	<u> </u>	<u> </u>	<u> </u>		<del> </del>
Transvaginal				ļ		<del>  -</del>	<u> </u>	ļ	ļ		<u> </u>
Transuretheral				<u> </u>		<u> </u>	<u> </u>	<u> </u>		ļ	<del> </del>
Intraoperative (specify)		<u>'</u>	<u> </u>	<u> </u>	<u> </u>	<del> </del>	ļ	<del> </del>	-		<u> </u>
Intraoperative Neurological		<u> </u>		<u> </u>	<u> </u>	<u> </u>	<del> </del>	<del> </del>		<u> </u>	<del>                                     </del>
Intravascular		ļ				ļ	ļ.—	<del> </del>	<u> </u>	<u> </u>	<b>↓</b> —
Laparoscopic				<u> </u>	l	<u> </u>			<u></u>	<u> </u>	

N = new indication; P = previously cleared by FDA; E = added under Appendix E

Alataa:	(2) Small	organ	includes	breast	testes	thyroid.

- [3] Cardiac is Adult and Pediatric.
- [4] Other use includes Urology/Prostate
- [\*] Combined modes are B/M, B/Color M, B/PWD, B/Color/PWD, B/Power/PWD.
- [+] RT3D is Realtime 3D / 4D volume tissue scan acquisition (with or w/o color flow);

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Traditional 510(k) Premarket Notification GE Vivid E9, January 19, 2012

### Diagnostic Ultrasound Indications for Use Form GE Vivid E9 with M5S-D Transducer

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

					Mode	of Op	eratio	n	<del></del>	· _	
Clinical Application  Anatomy/Region of Interest	В	М	PW Doppler	CW Doppler	Color Doppler	Color M Doppler		Combined Modes	Harmonic Imaging	Coded Pulse	RT3D Mode
Ophthalmic			ļ								<u> </u>
Fetal / Obstetrics	Р	P_	Р	Р	Ρ.	P	P	Р	P	Р_	
Abdominal	Р	P	Р	P	Р	Р	Р	Р	Р	Р	
Pediatric	Р	P	Р	. Р	Р	Р	Р	Р	Р	Р_	
Small Organ <sup>[2]</sup>							ļ				
Neonatal Cephalic		·		ļ							<u> </u>
Adult Cephalic	Р	Р	P	P	Р	P	Р	P	Р	P_	
. Cardiac <sup>[3]</sup>	Р	P	, P	P	P	P_	P	Р	Р	P_	
Peripheral Vascular			<u> </u>	<u> </u>		ļ	ļ	<b> </b>	ļ		
Musculo-skeletal Conventional			ļ	<u> </u>	ļ	<u> </u>	ļ	<u> </u>	-		<u> </u>
Musculo-skeletal Superficial			ļ			<u> </u>	ļ	↓	<u> </u>	<u> </u>	
Other <sup>[4]</sup>	P	P	P	P	Р	P	P	P	Р	P	ļ <u>.</u>
Exam Type, Means of Access			<u> </u>	<u> </u>	ļ	<u> </u>		<u> </u>	<u> </u>	<u> </u>	-
Transesophageal		ļ	ļ	ļ		ļ	<u> </u>	<del> </del>	<u> </u>	<u> </u>	<u> </u>
Transrectal			<u>.</u>	<del> </del>	1	<u> </u>	<b>↓</b>	<del> </del>	ļ <u>· · · · </u>	<del> </del>	<del>                                     </del>
Transvaginal	_		<del>  _</del> _			1	ļ	-	-	<del>  -</del> -	<del>                                     </del>
Transuretheral		<u> </u>			<u> </u>	<u> </u>		<del> </del>	<u> </u>	<del>                                     </del>	<del> </del>
Intraoperative (specify)		<u> </u>		<u> </u>	<u> </u>	-	ļ. —	<del> </del>	<del>                                     </del>	<b>├</b> -	<del>  -</del> -
Intraoperative Neurological		<u> </u>		<u> </u>	<del> </del> -	<u> </u>		<u> </u>	<del> </del>	<del>                                     </del>	ļ. <u> </u>
Intravascular		ļ		<u> </u>	-		ļ		<del>                                     </del>	<del> </del>	-
Laparoscopic						<u> </u>	<u> </u>	<u> </u>	<u> </u>		<u> </u>

N = new indication; P = previously cleared by FDA; E = added under Appendix E

Notes:	[2]	Small	organ	includes	breast,	testes,	thyroid.
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- [3] Cardiac is Adult and Pediatric.
- [4] Other use includes Urology/Prostate
- [\*] Combined modes are B/M, B/Color M, B/PWD, B/Color/PWD, B/Power/PWD.
- [ ] RT3D is Realtime 3D / 4D volume tissue scan acquisition (with or w/o color flow);

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Traditional 510(k) Premarket Notification GE Vivid E9, January 19, 2012

#### Diagnostic Ultrasound Indications for Use Form **GE Vivid E9 with 6S-D Transducer**

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

			.1		Mode	of Op	eratio	<u>n</u>			_
Clinical Application  Anatomy/Region of Interest	В	М	PW Doppler	CW Doppler	Color Doppler	Color M Doppler	Power Doppler		Harmonic Imaging	Coded Pulse	RT3D Mode
Ophthalmic											
Fetal / Obstetrics	Р	P	P	Р	Р	Р	Р	Р	· P	Р	
Abdominal	Р	Р	Р	P	Р	Р	Р	Р	Р	P	ļ. — .
Pediatric	Р	Р	Р	Р	P	Р	Р	P	Р	Р	
Small Organ <sup>[2]</sup>											
Neonatal Cephalic	<u>P</u> _	Р	P	. Р	, P	Р	P	Р	Р	P	ļ
Adult Cephalic			<u> </u>								
Cardiac <sup>[3]</sup>	P	Р	Р	P	P	Р	P	P	P	Р	<u> </u>
Peripheral Vascular								<u> </u>			<u> </u>
Musculo-skeletal Conventional			ļ	ļ							
Musculo-skeletal Superficial			ļ	ļ					<u> </u>		-
Other <sup>[4]</sup>							<u>'</u>		<u> </u>	ļ	
Exam Type, Means of Access				· ·		<u> </u>	ļ ·		<u> </u>	<u> </u>	<u> </u>
Transesophageal		ļ			1				<u> </u>	<u> </u>	<u></u>
Transrectal		<u> </u>		<u> </u>					<u></u>	<u> </u>	<u> </u>
Transvaginal				<u> </u>			ļ	<u> </u>		<u> </u>	<u> </u>
Transuretheral			<u> </u>		ļ		<u> </u>	<u> </u>	<u> </u>		<u> </u>
Intraoperative (specify)			<u> </u>	<u> </u>		<u> </u>	-				ļ.—
Intraoperative Neurological		ļ	<u> </u>	<u> </u>	<u> </u>	<u> </u>		<u> </u>			+-
Intravascular	•			<u> </u>	-	ļ		ļ			
Laparoscopic		<u> </u>	<u> </u>	<u> </u>		<u> </u>	<u> </u>	<u> </u>	<u>l</u>	<u> </u>	<u> </u>

N = new indication; P = previously cleared by FDA; E = added under Appendix E

Notes:	Ilem2 (C)	organ	includes	breast.	testes.	thyroid.
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- [3] Cardiac is Adult and Pediatric.
- [\*] Combined modes are B/M, B/Color M, B/PWD, B/Color/PWD, B/Power/PWD.
- [ ] RT3D is Realtime 3D / 4D volume tissue scan acquisition (with or w/o color flow);

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#### Diagnostic Ultrasound Indications for Use Form

#### GE Vivid E9 with 3V-D Transducer

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

	Mode of Operation												
Clinical Application  Anatomy/Region of Interest	В	М	PW Doppler	CW Doppler	Color Doppler	Color M Doppler	·	Combined	Harmonic Imaging	Coded Pulse	RT3D Mode*		
Ophthalmic							_						
Fetal / Obstetrics	Р	Р	Р	Р	Р	Р	Р	Р	Р	Р	Р		
Abdominal	Р	Р	P_	Р	Р	P	Р	Р	P	P	P·		
Pediatric .	P	Р	P	Р	Р	P	Р	Р	Р	Р	Р		
Small Organ <sup>[2]</sup>			<u> </u>	٠						-	Ŀ		
Neonatal Cephalic					<u> </u>								
Adult Cephalic	Р	Р	P	Р	Р	Р	Р	Р	P	P_	Р		
Cardiac <sup>[3]</sup>	Р	Р	P	Р	Р	P	. Р	Р	Р_	Р	Р		
Peripheral Vascular													
Musculo-skeletal Conventional											<u> </u>		
Musculo-skeletal Superficial						·					<u> </u>		
Other <sup>[4]</sup>	. <b>P</b>	Р	Р	P	Р	Р	Р	Р	P	Р	Р		
Exam Type, Means of Access								ļ					
Transesophageal			<u> </u>										
Transrectal													
Transvaginal													
Transuretheral													
Intraoperative (specify)							L				<u> </u>		
Intraoperative Neurological					<u> </u>	ļ <u> </u>	ļ. —						
Intravascular			<u> </u>										
Laparoscopic			<u> </u>				<u></u>						

N = new indication; P = previously cleared by FDA; E = added under Appendix E

Notes: [2] Small organ includes breast, testes, thyroid.

- [3] Cardiac is Adult and Pediatric.
- [4] Other use includes Urology/Prostate
- [\*] Combined modes are B/M, B/Color M, B/PWD, B/Color/PWD, B/Power/PWD.
- [\*] RT3D is Realtime 3D / 4D volume tissue scan acquisition (with or w/o color flow);

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#### Diagnostic Ultrasound Indications for Use Form

#### GE Vivid E9 with E8C-D Transducer

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows: .

	Mode of Operation											
Clinical Application Anatomy/ Region of Interest	В	M	PW Doppler	CW Doppler	Color Doppler	Color M Doppler			Harmonic Imaging	Coded Pulse	RT3D Mode*	
Ophthalmic										,		
Fetal / Obstetrics	Р	P	P		P	Р	Р	Р		Р		
Abdominal <sup>[1]</sup>	Р	Р	P_		Р	Р	Р	Р		Р		
Pediatric												
Small Organ (specify)												
Neonatal Cephalic												
Adult Cephalic									,			
Cardiac												
Peripheral Vascular												
Musculo-skeletal Conventional	·			<u> </u>	ļ	ļ		<u> </u>			-	
Musculo-skeletal Superficial			<u> </u>				·					
Other <sup>[4]</sup>	Р	Р	P		. P	P	Р	Р		Р		
Exam Type, Means of Access				,		<u> </u>						
Transesophageal			ļ			<u> </u>						
Transrectal	P	Р	P		P	Р	Р	P		Р		
Transvaginal	Р	Р	P		P	Р	Р	Р		Р		
Transuretheral			<u> </u>		<u> </u>	<u> </u>			,			
Intraoperative (specify)												
Intraoperative Neurological			<u> </u>		ļ							
Intravascular	<u> </u>					<u> </u>	<u> </u>					
Laparoscopic			<u> </u>						<u> </u>			

N = new indication; P = previously cleared by FDA; E = added under Appendix E

Notes: [1] Abdominal includes GYN/Pelvic;

- [4] Other use includes Urology/Prostate;
- [\*] Combined modes are B/M, B/Color M, B/PWD, B/Color/PWD, B/Power/PWD.
- [\*] RT3D is Realtime 3D / 4D volume tissue scan acquisition (with or w/o color flow);

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Traditional 510(k) Premarket Notification GE Vivid E9, January 19, 2012

#### Diagnostic Ultrasound Indications for Use Form

#### **GE Vivid E9 with 6VT-D Transducer**

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

·					Mode	of Op	eratio	n .			
Clinical Application  Anatomy/ Region of Interest	В	М	PW Doppler	CW Doppler	Color Doppler	Color M Doppler	Power	Combined	Harmonic Imaging	Coded Pulse	RT3D Mode
Ophthalmic											
Fetal / Obstetrics				,							
Abdominal				<u>.</u>	ļ						
Pediatric			<u> </u>								
Small Organ (specify)											<u> </u>
Neonatal Cephalic			ļ								
Adult Cephalic					ļ						
Cardiac	N	N	N_	N.	N	N	N	N	N	N	N
Peripheral Vascular					-				!		
Musculo-skeletal Conventional					<u> </u>					`	
Musculo-skeletal Superficial			<u> </u>								
Other (specify)				ļ						_	
Exam Type, Means of Access			ļ		<u> </u>		<u> </u>	ļ	·		<u> </u>
Transesophageal	N	N	N	N	. N	N	N	N N	N	N	N
Transrectal		·									
Transvaginal									-		
Transuretheral			:		,			ļ			ļ
Intraoperative (specify)			<del> </del>						<u> </u>		ļ
Intraoperative Neurological							ļ	<u></u>			ļ
Intravascular		<u> </u>									-
Laparoscopic		1	١.				<u> </u>			<u> </u>	

N = new indication; P = previously cleared by FDA; E = added under Appendix E

Notes:	[*] Combined modes are	B/M, B/Color M,	B/PWD or CWD,	B/Color/PW	D or	CWD,	B/Power/PWD.
	•					_	

[\*] RT3D is Realtime 3D / 4D volume tissue scan acquisition (with or w/o color flow);

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#### Diagnostic Ultrasound Indications for Use Form

#### GE Vivid E9 with 6T or 6Tc Transducer

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

. [					Mode	of Op		Y			
Clinical Application  Anatomy/ Region of Interest	В	. M	PW Doppler	CW Doppler	Color Doppler	Color M Doppler	Power Doppler		Harmonic Imaging	Coded Pulse	RT3D Mode
Ophthalmic	•		<u> </u>								ļ
Fetal / Obstetrics					<u> </u>					•	
Abdominal											
Pediatric								<u></u>			
Small Organ (specify)								<u> </u>			
Neonatal Cephalic			<u> </u>								<u> </u>
Adult Cephalic											
Cardiac	Р	Р	Р	Р	P	Р_	Р	Р	Р	P	L
Peripheral Vascular											
Musculo-skeletal Conventional		<u> </u>									ļ
Musculo-skeletal Superficial											
Other (specify)			<u> </u>					<u> </u>			
Exam Type, Means of Access				<u> </u>							
Transesophageal	P	P	P	Р	P	Р	Р	Р	Ρ.	P	
Transrectal											
Transvaginal											<u> </u>
Transuretheral				ļ							
Intraoperative (specify)			<u>'</u>						_		<u> </u>
Intraoperative Neurological									<u> </u>		ļ
Intravascular					<u></u>			,			
Laparoscopic		,			L						

N = new indication; P = previously cleared by FDA; E = added under Appendix E

Notes:	[*] Combined modes are B/M,	B/Color M,	B/PWD or CWD,	, B/Color/PWD or CWD,	, B/Power/PWD.
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[\*] RT3D is Realtime 3D / 4D volume tissue scan acquisition (with or w/o color flow);

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#### Diagnostic Ultrasound Indications for Use Form

#### GE Vivid E9 with 9T Transducer

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

					Mode	of Op	eratio	n			<b>,</b>
Clinical Application Anatomy/ Region of Interest	В	М	PW Doppler	CW Doppler	Color Doppler	Color M Doppler		Combined Modes	Harmonic Imaging	Coded Pulse	RT3D Mode
Ophthalmic											
Fetal / Obstetrics											
Abdominal											
Pediatric	•										
Small Organ (specify)			<u> </u>								
Neonatal Cephalic							_				
Adult Cephalic			<u> </u>			·					
Cardiac [3]	Р	Р	P	P	Р	Р	Р	Р	Р	Р	
Peripheral Vascular			·								
Musculo-skeletal Conventional		<u> </u>							_		<u> </u>
Musculo-skeletal Superficial									ļ		
Other (specify)	•	ļ.:							ļ		
Exam Type, Means of Access			<u> </u>					<u> </u>			
Transesophageal	P	P	P	P	Р	Р	P	Р	Р	P	ļ
Transrectal										_	ļ
Transvaginal					ļ. —						
Transuretheral	,							·			
Intraoperative (specify)			٠.	ļ				,	<u> </u>		
Intraoperative Neurological		<u> </u>	<u> </u>								ļ
Intravascular			ļ						ļ		ļ
Laparoscopic											

N = new indication; P = previously cleared by FDA; E = added under Appendix E

Notes:	[*]	Combined modes are B/M,	B/Color M,	B/PWD or CWD,	, B/Color/PWD or CWD,	, B/Power/PWD.
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[3] Cardiac is Adult & Pediatric

[\*] RT3D is Realtime 3D / 4D volume tissue scan acquisition (with or w/o color flow);

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#### Diagnostic Ultrasound Indications for Use Form

#### **GE Vivid E9 with P2D Transducer**

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

	Mode of Operation										
Clinical Application  Anatomy/ Region of Interest	В	М	PW Doppler	CW Doppler	Color Doppler	Color M	Power	Combined	Harmonic Imaging	Coded Pulse	RT3D Mode
Ophthalmic											
Fetal / Obstetrics					,						
Abdominal				,							ļ. <u>.</u>
Pediatric											
Small Organ (specify)	•										
Neonatal Cephalic					<u>.                                    </u>						
Adult Cephalic			1								ļ <u>.</u>
Cardiac <sup>[3]</sup>			Р	P		ļ		·	i		
Peripheral Vascular			P	Р							
Musculo-skeletal Conventional		<u> </u>									
Musculo-skeletal Superficial										•	
Other (specify)		<u></u>	•						·		
Exam Type, Means of Access			ļ								<u>                                     </u>
Transesophageal		, <u>-</u>			<u> </u>						,
Transrectal			ļ	,				,			
Transvaginal			ļ			1, 1,					
Transuretheral											ļ <u>.</u>
Intraoperative (specify)			1						٠.		
Intraoperative Neurological											<u> </u>
Intravascular											
Laparoscopic						<u> </u>					

Motoe.	[3]	Cardiac	ie ,	Adult	and	Pediatric.
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[\*] RT3D is Realtime 3D / 4D volume tissue scan acquisition (with or w/o color flow);

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#### Diagnostic Ultrasound Indications for Use Form

#### **GE Vivid E9 with P6D Transducer**

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

	Mode of Operation							on				
Clinical Application Anatomy/ Region of Interest	В	М	PW Doppler	CW Doppler	Color Doppler	Color M Doppler			Harmonic Imaging	Coded Pulse	RT3D Mode	
Ophthalmic						٠						
Fetal / Obstetrics											<u> </u>	
Abdominal										<u> </u>		
Pediatric											<u> </u>	
Small Organ (specify)												
Neonatal Cephalic			<u> </u>									
Adult Cephalic											<u> </u>	
Cardiac <sup>[3]</sup>			Р	Р	<u></u>						<u> </u>	
Peripheral Vascular			P	Р					•			
Musculo-skeletal Conventional							ļ				<u> </u>	
Musculo-skeletal Superficial											<u> </u>	
Other (specify)					<u> </u>						ļ	
Exam Type, Means of Access											<u> </u>	
Transesophageal							ļ <u> </u>					
Transrectal											<u> </u>	
Transvaginal	:										<u> </u>	
Transuretheral				<u> </u>							ļ	
Intraoperative (specify)						<u> </u>	ļ	1	_		ļ. —	
Intraoperative Neurological												
Intravascular			<u> </u>								↓	
Laparoscopic	_	l						<u> </u>			<u> </u>	

N = new indication; P = previously cleared by FDA; E = added under Appendix E

Notes:	[3]	Cardiac is	: Adult	and	Pediatric.
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[\*] RT3D is Realtime 3D / 4D volume tissue scan acquisition (with or w/o color flow);

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